Certification and Adoption Workgroup
Draft Transcript
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Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Great, thank you. Good morning, everybody, and welcome to the Certification and Adoption Workgroup. This is a federal advisory committee workgroup, which there will be opportunity at the end of the call for the public to make comment. Let me do a quick roll call. Paul Egerman?

Paul Egerman – eScription – CEO
Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director
Marc Probst?

Marc Probst – Intermountain Healthcare - CIO
Yes, I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Adam Clark?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Charles Kennedy? Scott White?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Latanya Sweeney? Micky Tripathi? Joe Heyman? Harry Tuki? Carl Dvorak? George Hripcsak? Joan Ash? Chris Brancato?

Chris Brancato – Deloitte – Manager, Health Information Technology
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
William Munea? Okay, and I know, I did hear, Paul, and I think you did too, Rick Chapman was not able to make it, nor was Steve Downs.

Paul Egerman – eScription – CEO
Okay.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anybody else on the line that I missed? Okay, Paul, I'll turn it to you, thanks.

Paul Egerman – eScription – CEO
Yes, thank you very much, Judy. Good morning, this is Paul Egerman; welcome you to our conference call for the Adoption/Certification Workgroup. We actually have two topics today. I know many people are very interested in the patient safety discussion. Also before I talk about the agenda, I should have also said that I want to welcome any many of the public who might be listening in. So thank you if you're listening to this call, thank you for your interest in our work. We will have a time for public comment at the end of the call.

The two topics that we have for our agenda, one of them is patient safety, which is I know a topic that there's a lot of interest in; but we have a second topic that we also have to go through, which is the certification NPRM. The situation is that a NPRM was published in the federal register a few weeks ago and was based upon the recommendations of this workgroup. We didn't know the timing of when it would be published, and it was being published based on our recommendation, and it has both a temporary certification program and a permanent certification program.

The temporary certification program has a very short comment period and comments are due by April 9th from the temporary program. And since we were the ones that made the recommendations that were at the core of a lot of what was written, it seemed like it was reasonable that we should make comments if any on the NPRM.

I would say the general comment in my opinion; ONC did a really excellent job. They did it exactly at a high level of what we had recommended. They created a certification process that is more objective than I think— there had previously been some controversies around CCHIT, and then possibly its relationship with various aspects of the industry. And I think this new process sort of eliminates any of those issues and creates a process that the public can have confidence in.

I'm personally very excited by it. But what I think we should be doing is walking through some of these issues that I laid out in the document where ONC had requested public comment to see if we want to comment on them. And then when we're all done with that, hopefully, there still will be time, we will continue our discussion with patient safety.

Before we dive into our comments today, the workgroup members, are you comfortable with this as an agenda or is it a way to proceed with this matter?

M
Looks good, Paul.

Paul Egerman – eScription – CEO
Okay.

M
I agree.

Paul Egerman – eScription – CEO
What I tried to do, and again, if the members of the public who might be listening in, what I tried to do with this document was to put it on the HHS Web site, I took the NPRM and I extracted out the sections where it appeared that ONC was asking for comments, so that's what I did. Again to make sure everybody understands this, it's comments on the temporary program. We get an opportunity to make comments on the permanent program if we want in another month.

Now on each of these questions, it looks like there are seven of them. I also want to tell you, the members of the workgroup, we do not have to make a comment. In other words, we could read something and say, we don't have anything to say. So it's not like we're required to make a comment, but it seems like if ONC was asking for advice, that might be an opportunity.

The very first one that was written was basically dealing with modules. And if I read this correctly, it says a requested comment on whether or not when they test and certify a module, whether or not they should also be testing and certifying that a module will work properly with other EHR modules presented, perhaps by a different EHR module developer. What do you think about this issue?

George Hripcsak – Dept of Biomedical Infor Columbia Univ - Chair
Paul, this is George. Sorry, I wasn't here for roll call. What's the issue on that, I know, I was trying to go over it, but what exactly is the question?

Paul Egerman – eScription – CEO
It's actually a very interesting question. Basically it says, if somebody submits a module for testing and certification, if that module passes testing and certification, should the certification entity also be required to test to see if that module will work with other modules that perhaps some other developer created?

Marc Probst – Intermountain Healthcare – CIO
Paul, is that external to a specific environment? In other words, one healthcare system, how are they going to know the basically infinite number of integrations that would have to occur?

Paul Egerman – eScription – CEO
That's a good question, and I think that was Marc who said that.

Marc Probst – Intermountain Healthcare - CIO
It was.

Paul Egerman – eScription – CEO
One administrative comment, since we're on a public line, please state your name before you talk. My answer to that, your question, Marc, I think that's a good question, because when I read this, my thought was, it'd be great if they did this, but I couldn't figure out how they could possibly really do this and do it right.

Joan Ash
This is Joan, I'd like to weigh in on this too. I made a little note that it seems like this would be impossible right now. So would it be possible to put this on the back burner for awhile?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang. I also when I heard it, I thought how could someone do that? The only thing I could think of is to look at how well the interface is spelled out and whether there is a good definition to allow you in a semantic integration with other modules and products, that's a hard thing to test. But you could see how without demonstrating that you have an open ATI for example, that would be one criteria for saying, "Well gosh, I don't see how this would plug into other modules."

This also raises the question of how, I know we recommended this to HHS, but how robust of a recommendation is this that we allow modules? Because certainly the comments that have been seen in the media, can you really assemble on your own a bunch of modules and come out with a comprehensive and safe EHR for that matter?

Paul Egerman – eScription – CEO
Those are all great comments. The sense I have from what everyone's said so far, we don't understand a practical way to do it based on the very sort of generic way it's stated. The only way I can think of that one could actually accomplish this could possibly be if you define certain modules that you wanted tested with certain other modules.

So for example, if you said, "Well gee, if one of the modules is CPOE or if one of the modules is ePrescribing, then the following other modules should be tested with it." Whereas, if you were very explicit I suppose you could do it, but just saying the way it's said here, I'm sort of at a loss as to say anything other than something like a good idea, but we don't know how to do it.

Chris Brancato – Deloitte – Manager, Health Information Technology
Paul, this is Chris Brancato. I think your last sentence there raised a good point. I want to point out that as we're standing up the certification program and writing the test methodology with NIST, we walk a fine line where we cannot introduce new requirements other than what's been elaborated in the rule. So that's going to be true for everything we discuss here.

Paul Egerman – eScription – CEO
So if I heard your comment, Chris, then you're saying we could not say if we wanted to that, "Gee, you have to test ePrescribing against a patient registration."

Chris Brancato – Deloitte – Manager, Health Information Technology
Yes, to put a finer point on that, that's exactly right. So if the rule is not specific, there is an expectation of integration. We can't write that requirement into the certification program.

Paul Egerman – eScription – CEO
Okay, so then maybe our response to this is to say that we don't understand. There is not a good mechanism to do this, so that they should not be expected to test the modules against other modules. But then also to suggest that this might be an area that this group explores for future stages as to methodologies for doing this, the module compatibility. This is an area that we need to do some additional work for future recommendations.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang. My concern about that is that the ability to pass modules as certified, which invites people to purchase these things, could also be misleading them into believing that you could reassemble these things into a functional module that qualifies for meaningful use.

So for example, one of the early standalone kind of functions is ePrescribing. If you can't integrate it with other aspects of an electronic health record system, then you wouldn't be able to deliver interactions between drugs and lab test results or drug and diagnosis, etc., which is part of what you would like to have in ePrescribing, the position support associated with that.

Now if someone purchasing the ePrescribing module or product could misinterpret a certification as saying this would fit in with other EHR components. And it seems like somewhere along the lines somebody has some responsibility of saying are the standards and interoperability practices available today, permit you to assemble a complete EHR using these certified modules?

Paul Egerman – eScription – CEO

Yes, listening to what you're saying, Paul Tang, I wonder if another way to respond to this would be to say that the certification of modules should include somehow a labeling requirement that says certification means that interoperability hasn't been tested and hasn't been certified.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think you're on the right track. I think that's a way to help inform and educate the public and potential purchaser. We certainly would want to apply the existing interoperability requirements, the use of standards in the interfaces going in and out of that module to be in place. So there are some things that we can say.

For example on a comprehensive EHR, I think in a previous discussion, we said we aren't going to interfere with how data is exchanged from one module component inside of that complete EHR. But clearly for a standalone module, you would want to certify the ATI to all of them to be standards compliant to the existing standards.

Paul Egerman – eScription – CEO
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Which your labels are good too.

George Hripcsak – Dept of Biomedical Infor Columbia Univ - Chair
This is George Hripcsak. It's not a feasible task to do. At some point, we're going to have to use the old fashion system where the vendor makes a claim that it can do xy&z, and then the users trust it, and then it either works or it doesn't work, but nothing is guaranteed in life. In other words, I don't think we can certify every last possible combination or detail.

I think from the beginning, we can't start with the assumption that certification is going to solve the problem of how do you get one system working or multiple systems working together. And I think that having buyers be aware, so I think that's good what you just said, that here's what the certification tells you, here's what the certification doesn't tell you, and you need to consult with the manufacturer about it. I don't know how to put it exactly and how to help them, but if we take on a task that we can't succeed on, that won't help anybody.

Paul Egerman – eScription – CEO
That's right and we don't want to mislead people.

Suniti Ponkshe – IBM Global Services – Associate Partner
Paul?

Paul Egerman – eScription – CEO
Yes.

Suniti Ponkshe – IBM Global Services – Associate Partner
Paul, this is Suniti. I guess one suggestion I might make is that this is addressing public comment and one of the comments could be that this should be included in part of the testing guidelines or testing criteria that when different modules come together, the part of the testing guidelines and criteria could be that they're tested to work together. Because ONC is working with NIST on developing the testing guidelines and the testing infrastructure.

Paul Egerman – eScription – CEO
Right, but it's still, as Marc Probst says, it's hard to test modules, especially modules from different developers independent of having an environment to test them in. It does seem to me, based on the status of how interoperability works right now, what happens like if I'm the vendor and I've got a module, and you go through this process, and the certification bodies as well, "Congratulations, your module passed all the testing criteria, but it doesn't work with this module that this other guy created, so therefore, we can't certify you." If I'm the vendor I'd go nuts, I'd say, "Hey, I did everything that was in the regulations, don't certify the other guy, certify me."

I think the current status of things, I think the certification entity is in an impossible situation.

Marc Probst – Intermountain Healthcare - CIO
Paul, this is Marc Probst. I think Paul Tang hit on some good points though, and I as a receiver of these modules would be very interested that there's an open ATI. I don't know what the standards are specifically, Paul Tang, but it's not in every instance that even that module has an open ATI where you can do the integration.

Paul Egerman – eScription – CEO
So what should happen there, should there be some requirement for an open ATI, a labeling about an open ATI, how do we respond to that?

Marc Probst – Intermountain Healthcare - CIO
I don't know, I'm just coming up with the problem.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
So one, Paul Egerman, I think you made an important point that if they're going to certify modules that there needs to be not a disclaimer, but an educational piece that what does this mean? How should the perspective user interpret the certification of a module?

And the second point is, when you do have interfaces with the module that is exposed to the public, i.e., not as part of integrated product, then it does have to comply with all the relevant standards.

So with ePrescribing, it maybe NCPDP, overtime it may involve the use of RxNorm, if it has to do with labs, it would be LOINC, etc. So those are things, which aren't automatically guaranteed inside an integrated system, but we govern all of the interfaces with the outside world; and in a module most of its interfaces are going to be exposed, so they have to be compliant with the existing standards at the time.

Paul Egerman – eScription – CEO
Okay. I just wanted to make sure that I got this right. So basically the way we're going to respond to this is to say that this is sort of a current state of technology. The certification agency should not be trying to certify modules against other developer modules. But there should be for module certification a labeling requirement that provides education and it describes what reasonable expectations are for interoperability with other applications, and also what has been certified, and what has been tested and certified in terms of ... what you just said, Paul Tang, about which standards have been tested against.

Does that sound like the right response to this issue?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's the right direction, I think the wording has to—

Paul Egerman – eScription – CEO
Yes, the wording is going to take a little bit of work.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes.

Paul Egerman – eScription – CEO
Okay. Let's move onto the next question. The next question, basically the way that the certified process works, these authorized organizations can certify modules or they can certify a complete EHR. And the question is should there be like a third type instead of just modules?

And complete EHRs, can they be organizations that certify for example only an ambulatory or a physician EHR, so that that would be a third type, and there might be a fourth type that says only complete EHRs for hospitals. So that's the question, should there be separate certifying agencies that can do, for example, complete EHRs for ambulatory? Does the silence mean nobody has any response to this issue?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Hello, Paul, it's Scott. My only comment is that if we fragment it, do we not water it down in the process, and almost, I don't know, I'm just thinking about too many certifiers out there. I don't have an answer, it just seems to be more problematic the other way.

Paul Egerman – eScription – CEO
Yes. Essentially, I had some communication with Joe Heyman on this issue, Joe told me to make call. But the issue that he and I sent e-mails back and forth on was as you look at the vendor community, there are a lot of vendors who only sell physician systems, that's all they sell.

Certification for the physician, complete EHR systems for physicians, the testing certification process is a lot easier on the physician side than it is on the hospital side, because there's just less complexity, there's less stuff to do. So by creating an opportunity for a certification organization to become a certifier of physician systems radiates EHR physician systems, that could be an entry task for a new certification organization.

Let me pause here and let the people think about that. I guess silence means nobody has any comment.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul, I'm not sure I'm actually understanding the question in full.

Paul Egerman – eScription – CEO
Let's look at it this way, there's a lot of vendors, I hate to ever name a vendor, but there's a lot of vendors who just sell to the physician marketplace, who do not sell to hospitals.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right.

Paul Egerman – eScription – CEO
And in fact, there's a lot of small vendors who do that, that's the way you can get into this whole industry. A number of people are concerned that there might be too many certification organizations, but the flipside of that concern is maybe there will be too few. It's hard to become a certification organization, if you have to do everything, maybe a lot of people won't do this.

So the question is this, can you become a certification organization and do complete EHRs, but just do it for physician systems without doing it for hospital systems?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
When you say complete EHRs, what you basically mean is, can you be a certifier of only ambulatory EHRs to start with?

Paul Egerman – eScription – CEO
Yes, that's correct.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay. It's a free world, anybody can choose to do that, right?

Paul Egerman – eScription – CEO
Not quite, because according to the way this is written, you can only certify either a complete EHR or modules.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Oh, I see.

Paul Egerman – eScription – CEO
If you wanted to do a complete EHR for ambulatory or physicians, you'd have to certify every module, you could do that, but then you'd have to issue certifications I assume with the labeling stuff we'd just agreed to. And so you don't have a way to do this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do the drafters possibly just think of an ambulatory EHR as potentially a module and that modules might be small, medium, and large, is that how it's written maybe, just the accident of writing?

Paul Egerman – eScription – CEO
That's a creative solution to that issue. I guess my view is I do think it would be advantageous for a certification group to be able to do this and certify just the physician side, because that's as I say, it's a way for them to start doing the certification and testing without having to do all the inpatient complexity.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Paul, it's Scott again. Provided that they were under I guess the umbrella, I guess it would be ... we were talking about as being the leader of the certifier groups. It would be a way to address what I've been fearing, which would be a large cue on testing all these organizations. I guess my reaction is that it would be, if everybody is testing on the same level of accountability, it should be a good thing then to have more and break it down as you said in this example, just an ambulatory setting. I think I'm in favor of it.

Paul Egerman – eScription – CEO
Does anybody not like it and think it's a bad idea?

Joan Ash
This is Joan, and I agree, I think it's a good idea, because then certain certification agencies would be able to really, really specialize. They would be in a niche and I could see an advantage to that.

Paul Egerman – eScription – CEO

Okay. So we'll just go ahead and say, yes to that one, and I'll write up a recommendation on that. What we'll do when we get through all this, I'll write up some wording on this, and send out a word document, which everyone can do their best to edit. I appreciate those comments.

The next question deals with the location where testing occurs. Basically for the most part, the current state-of-the-art is the testing really occurs at the facility that does the testing, which is actually an aspect that adds to the cost from the standpoint of the vendor. And then the section describes a whole series of things where the testing could occur either remotely, in other words, from some process where you can see the screens at another location or perhaps somebody goes onsite, which would be a good idea for like self-developed systems. Because the self-developed organizations probably don't have the capability to do the testing at a different location that a vendor might have.

And so the question is they request public comment on whether an authorized testing certification organization should be required to the form, what they call secondary methods in addition to certifying at its own facility. So the question is this a requirement to be a certification organization and you should be able to do things remotely? Any comments on that?

Joan Ash
This is Joan. And I think since we're supposed to be talking about HIT safety, this is one way to really push the safety part of it, because the safest system will be the one that's there onsite and installed.

Paul Egerman – eScription – CEO
That's an excellent comment. So you're saying, yes, it should be required?

Joan Ash
Yes.

Paul Egerman – eScription – CEO
Anybody disagree?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul, again, let me make sure I understand the question, I thought the original question was whether a certifying organization should be prepared to certify remotely versus certify in person?

Paul Egerman – eScription – CEO
That's right. It's really whether or not they're prepared to certify outside their own facility.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The facility being the certifying agencies facility.

Paul Egerman – eScription – CEO
That's right. In other words, if I am located in Washington DC, I'm a certifying organization, do I have the right to say, if you want to get tested and certified, come to me, or should I be required to say, one can come to me, but there are some circumstances under which I'll come to you or I'll do it remotely? I may not travel, but I'll be hooked into your computer terminals.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, sure. Having done this with CCHIT, I think remote certification is a very reasonable and efficient method. I guess I would require that certifying organizations be prepared to certify remotely. I don't know that the being in person is actually the right thing to do, because you really either have to pack up a

bucket load of technology to drag out and set up somewhere or what you'll end up doing is remotely dialing back into a facility anyway. So I would suggest that certification agencies be prepared to remotely certify.

Paul Egerman – eScription – CEO

Okay, that's great, so I think we have an agreement on that. I have one other comment in my notes when I write this up I'm going to include, which is they gave a number of examples, and they gave you examples of the really self-development. And I was also going to put in there a suggestion that they give Open Source as another example as to where the remote certification would make sense. And then probably, because I think it's a good example, but also I think somehow there's a tendency to get it up to the Open Source community in all of these things and it would be nice to at least mention them as an example. So that's my comment there.

The next question that we have has to do with this minimum standards issue. It's actually a very interesting question and there's like a page description of it all. But what minimum standards is all about is basically in the IFR, I think it's really primarily for what they call vocabulary code sets, but it also exists for or could exist for actually interface standards. There is concept that a certain version number represents the floor, so you could say version 3.5.1 or something is the minimum standard, but the concept is subsequent revisions are also acceptable according to the regulations.

So the question becomes fundamentally, how does that really work? Who decides when a subsequent revision is really acceptable and who decides when the testing criteria will be changed? And then this section describes like two capabilities if I understood it right, one was that members of the public could make comments to the secretary and the secretary would consider those comments, perhaps get advice from the standards committee, and then quarterly issue some update. And the second concept was, I guess the second concept was going through the standards committee, I'm not sure.

It creates two concepts here. So the question is how do you identify when a newer version of the minimum standard is acceptable as part of the certification? I guess that's the way it's saying, that that's what the question is. Do we have any comments on this?

It's starting to get really deep into the weeds with the technical stuff or the technicalities of this. The silence means nobody has any comments on it?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I guess I'm struggling a little bit to ... the background from the formal question. How would we state the formal question on that one?

Paul Egerman – eScription – CEO

If I could read what it says, we seek public comment, which is on whether other methods we might take to identify acceptable newer versions and minimum on the standard code sets, in addition to two methods, we have discussed. So the two methods are basically, one of them was comments from the public and the other one was for the secretary to proactively identified newly published versions. So one was receiving comments from the public as to when there's a new version and the second one was the secretary. I guess it really means ONC goes out and proactively decides that here's a new version, and I guess you could do both.

Does that answer your question with the formal comment what the question was? The question was, are those two methods good enough or is there another methodology for doing this to get the newer versions?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
So the question is how do we gain consensus that a new version of a terminology or standard like that is required for certification? And the choices are ONC says so, public comment, aren't those two good enough?

Paul Egerman – eScription – CEO
Yes, the choices are basically ONC reacts to public comment or number two is ONC is a little bit more proactive and—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Deems it necessary?

Paul Egerman – eScription – CEO
Deems it necessary, yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And that would be through the current standards group and it operates at the time?

Paul Egerman – eScription – CEO
Yes. Well I assume so. I assume that it would either way you get, from the standards group, it's like our group, it's an advisory group, so I think it would—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I would assume if it's a national standard, having it come through ONC for the time being is the right choice, and they'll have to convene or maintain a standard setting group like a HCPCS previously that would propose those, right?

Paul Egerman – eScription – CEO
That's right. The only question I had about this is where some of these standards like LOINC, aren't there entities that somehow already do this? Isn't there some group?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Entities that maintain it and promote it. The real question though is who will sit in judgment of requiring it as the new law of the land that everybody do it?

Paul Egerman – eScription – CEO
Well, yes, although, if there's entities that promote it, I mean, another way to do this would be to say, if there's an entity, that sort of takes care of it all once they define something that's new for LOINC, that automatically becomes the new one.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I don't know if I would recommend against that. I think what you'll sometimes see is that just because the last one worked out okay, doesn't necessarily mean that everything they do in the future would be appropriate or agreeable. I think HL7 was a good example, they sort of ran off a cliff by accident with some of the room, the version 3 stuff, because it really wasn't baked well enough when it first came out to work. So I don't know that you'd want to say LOINC is good today, and then whatever the LOINC people decide for the future is the law or the rule. I think there still needs to be a filtering process to make sure that what they devise in the future still makes sense in context for the national objectives.

Paul Egerman – eScription – CEO
Okay, so you're saying the way this is written is fine.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think so.

Paul Egerman – eScription – CEO
Okay. So we could either respond by not making a comment or we could respond by saying we're comfortable with what you said. Because I think that that also could be of some value for ONC to know that we really felt comfortable, so we should just say we like what's written, unless somebody objects, we'll go onto the next one.

The next question is interesting. This is the question about revoking basically a status of a certification and testing organization. The question is if somebody repeatedly commits a type two violation, I guess it's the national coordinator for the temporary program, can the national coordinator decide that automatically based on a certain number of type two violations that their certification and testing status is revoked?

And so when I reread that, the first question is what's a type two violation? And that's sort of like a quiz on how well anybody's read this thing. But a type two violation can be, Suniti, tell me if I've got this right, but it's like missing a meeting, but it's also violating like a code of conduct. It could be like perhaps not doing the testing correctly, am I describing that correctly? Suniti?

Suniti Ponkshe – IBM Global Services – Associate Partner
I think so.

Joan Ash
Yes.

Suniti Ponkshe – IBM Global Services – Associate Partner
Yes.

Paul Egerman – eScription – CEO
Oh, yes, it says here you have to adhere to principals and proper conduct, and so the violations are failing to attend a mandatory ONC training program, failing to meet specified reporting requirements or misrepresenting the scope for this authorization. Those are the examples.

So the question is, should there be a certain number of these over a certain time period that automatically would cause the national coordinator to revoke the authority for an organization to do things. This may seem like a real technical question, but it's actually very important, because if there's somebody who's not doing stuff correctly, if we let that continue we're going to lose public confidence in this program.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang, I think they have to be able to do that for reasons you suggested, but it also ties into the second part of this discussion this morning, which will be the EHR safety in which we sort of, one of our proposed recommendations is that we try to ensure safety through the certification of EHR process. And that's both the process of developing the software, as well as the reporting requirements of safety incidence. Without this kind of teeth, that is you can revoke something, then I don't know that it would be safe enough to allow just certification to be sort of the backstop for EHR safety.

Paul Egerman – eScription – CEO
Right.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And the other piece is, it does use the word repeatedly, and we earlier today talked about the disclaimer where you have to explain if you're just a certified module that that doesn't guarantee that actually the functions that we demonstrate in this module will actually be useable or meaningful in the context of wherever you're going to plug it into.

And for them to let's say not post that disclaimer or misrepresent it, "Oh, sure, we're certified," you'll definitely get your incentive, etc., then that would be another grounds where you'd want the certification to be revoked. So I think they need this authority.

Paul Egerman – eScription – CEO
Yes, those are good comments, Paul. But the question is not whether or not they have the authority, the question is for those called type two violations, is there a number of those that automatically cause you revoking? In other words, is this one of the things where we would say, three strikes and you're out and give a specific number?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Paul? Paul, it's Scott. Is it too harsh to consider one and done? And thereby holding to a very high level of accountability, will we give a better impression of patient safety that these guys have to adhere to the highest levels of accountability or is that just not part of the conversation and unfair to hold them that high?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang, I'm not sure that, I would rather give ONC or the secretary the discretion to be able to fit the punishment to the crime. In other words, there are some egregious conditions where you might do a one and done. There may be others where you give them a chance, but the secretary should be able to revoke it when they feel that there's not a good faith effort on the vendor to comply with the certification standards that they under which they were certified.

George Hripcsak – Dept of Biomedical Infor Columbia Univ - Chair
This is George Hripcsak. If you have one certification agency that has a thousand employees who's doing every record in the country, and another one who has five employees, to hold them to the same number of violations maybe doesn't make sense. It depends on the whole record, so I think there needs to be some interpretation on ONCs part. So you're saying they already have the authority to terminate presumably on any type violation, and I would caution against us picking a number, because we really have no idea what that number should be. We don't know what it's going look like.

Paul Egerman – eScription – CEO
Okay. If I'm hearing this right, the consensus is we don't want to set like a hard and fast rule. We don't want to say one and done, three strikes and you're out, but we do want the national coordinator to make a subjective judgment and say, depending on the nature and the intensity of the violation, the frequency that they could go ahead and revoke the status of these type two violations. Is that correct?

George Hripcsak – Dept of Biomedical Infor Columbia Univ - Chair
I think so.

Paul Egerman – eScription – CEO

Okay, great. So then the next question that was listed here is, let's see if I've got this one right, Suniti. It lists this concept that you have stage one, stage two, and stage three of meaningful use and presumably that also means you're going to have stage one, stage two, stage three of these IFRs. And the issue is a timing issue, which is what happens if a physician group or a hospital starts late and they start in 2013, then wanting to do stage one of meaningful use, and the only software that's available for them to buy is stage two certified though. Do they have to buy stage one software or can they buy like stage two software and still do stage one as meaningful use? I think that's what I understand the question to be. What are reactions to that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think anything you provide at a higher level should qualify.

Paul Egerman – eScription – CEO
Yes, I agree. The way I look at that issue is it shouldn't be a problem, because if somebody is starting late and they're starting, then they should go ahead and buy stuff at stage two or stage three certified, because eventually they hope to get to stage two or three anyway. So all they're going to get is extra stuff they don't need to do for stage one, but they should go ahead and do it.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Paul, it's Scott. Is this question similar to some responses that Tony Trenkle has given regarding really the funding of this issue in that you almost can't look back, you have to start it at the level that the calendar is, if I remembered Tony's comments correctly. So those seem to be parallel conversations for me.

I wasn't sure my phone was still on.

Paul Egerman – eScription – CEO
You've got to correct me if I've got this wrong, Paul, a group can start late and they can start with stage one. They only have to start at stage two of meaningful use if they haven't done stage one yet. Is that right?

Suniti Ponkshe – IBM Global Services – Associate Partner
Paul, this is Suniti In the CMS rule, there is staggered schedule that they have about by what time, like how they could get to stage one and stage two and three, and I'm thinking one of the public comments could be that the criteria should align with those requirements, that way they're all consistent.

Paul Egerman – eScription – CEO
That's true, Suniti, but even if the criteria aligns, to me there's no problem with buying stage two software even though you haven't yet done stage one qualifications, because eventually you're going to want to do stage two anyway. You shouldn't have to like buy an old version and then upgrade it.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Well inclusive.

Chris Brancato – Deloitte – Manager, Health Information Technology
This is Chris Brancato. The premise was and I think if you look at the rule, it's elaborated pretty clearly that stage two certified products must include stage one certification.

Suniti Ponkshe – IBM Global Services – Associate Partner
Yes.

Paul Egerman – eScription – CEO
Okay.

Chris Brancato – Deloitte – Manager, Health Information Technology
So there's an iterative process, so if you look at the table on CMSs rule, a stage three certified product would also have to comply with stage one and stage two.

Suniti Ponkshe – IBM Global Services – Associate Partner
Yes, it's a stair stepping kind of approach.

Paul Egerman – eScription – CEO
Okay. So I think then if I understand the question right, maybe I'm not understanding it right, there's not a problem there, as long as we have this iterative stair stepping approach, it doesn't strike me that there's any issue with the staging process.

Chris Brancato – Deloitte – Manager, Health Information Technology
Chris again, I think there's another point to this and I think you're getting to it, and that is from a consumers point of view, a vendor offers them a stage two, the promise of a stage two certification, but the rule hasn't come out and have been finalized, and we haven't developed the criteria for stage two. It's a vis-a-vis, what the HIT is doing today, and not just them, other that we're going to certify the stage one criteria and we're going to make sure your product is certified.

Paul Egerman – eScription – CEO
So you're concerned about like a labeling issue?

Chris Brancato – Deloitte – Manager, Health Information Technology
No, I'm not concerned at all. I was just recognizing from the consumer point of view that to Tony's point, there's an official, the rule comes out and becomes final, the certification program gears up, the ATCBs implement down to the testing labs, and then the testing labs officially test for stage two criteria. And until that happens, everything in the vendor community that says they're going to be stage two certified is almost a promissory note, but it hasn't happened yet.

Paul Egerman – eScription – CEO
So does that suggest then that part of our answer to this question is that there needs to be clear labeling that says what stage or stages the software has been certified for?

Chris Brancato – Deloitte – Manager, Health Information Technology
I obviously can't suggest one way or the other, because of my relationship with ONC.

Paul Egerman – eScription – CEO
Okay, so I'll ask the other workgroup members then.

Chris Brancato – Deloitte – Manager, Health Information Technology
Okay.

Paul Egerman – eScription – CEO
If I heard Chris's commented correctly, one of the risks that we're running with all the staging is confusion as to whether or not, what stages of the software has really been certified against? And as I think about it, that may not be the question, but that could be a possibility when somebody says, I'm certified by HHS,

and they got certified in stage one. Now the stage two stuff has actually been announced, and they're still selling themselves as certified, but they really haven't been tested against stage two.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
So it's not clear by their labeling?

Paul Egerman – eScription – CEO
The issue is certification can include labeling requirements.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, it should I guess.

Paul Egerman – eScription – CEO
And so maybe we should say certification should clearly state what stages of the process that that software has been tested and certified to comply with or whatever to conform with, whatever the right wording is.

Joan Ash
This is Joan. So we're talking about truth in advertising here on the part of the vendor selling the product?

Paul Egerman – eScription – CEO
Well, yes.

Joan Ash
Okay.

Paul Egerman – eScription – CEO
That probably is, I wouldn't use that expression, but that, I mean labeling as I read this document, is one of the things that's included in certification. It's like FDA has labeling rules and so I think you can labeling rules as part of this process. And it sounds to me from Chris's comment that that would be a useful thing.

Chris Brancato – Deloitte – Manager, Health Information Technology
Yes, I think we have two things, one is we need to have the truth in advertisement to know exactly what has been certified, but the other is that means there needs to be an ONC educational effort to make sure people do understand the program as best they can. When the final rule comes out, I think, once we know what the final rules are, then there probably will be a set of communication tools and educational tools that will help people understand that cascading, that stair step kind of certification criteria, meaningful use criteria, and then what do you look for in the labels.

Paul Egerman – eScription – CEO
Okay.

Chris Brancato – Deloitte – Manager, Health Information Technology
But all this would have to come together.

Paul Egerman – eScription – CEO
Okay.

Chris Brancato – Deloitte – Manager, Health Information Technology

But at this point, it's easy to get confused here.

Paul Egerman – eScription – CEO
Okay, so not hearing any objection, when I do my draft response, I'm going to put in like the response to this labeling recommendation in terms of labeling which stage, what's tested against, and as a result, what stages that software can be used by users to comply with meaningful use, because I can see where there could be a lot of confusion.

The last issue on the list and I'll also make a side comment, the last issue on my list, there was actually one other issue that I didn't include in this list, which is a long discussion on about privacy and security. And what I did was I copied all of that and gave that over to the privacy and security workgroup and asked them to comment on it, because actually they have been discussing that issue. And we're free to comment on it also, but they're actually going to have a discussion on that in a couple of hours.

So the last one on my list had to do with, they had requested public comment on establishing a date for when the temporary program would, they said sunset, and whether or not they should choose a specific date, like December 31, 2011, or if they should target the date based on when the first authorized certification organization is created under the permanent program. In other words, should it just be a specific date or should it be when there's at least one certification organization that's ready to do permanent certification. Is this a question we want to weigh in on and have any comments on? Does the silence means that we don't care and we're just going to leave this issue alone?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Paul, it's Scott. Can you just reframe the issue again for me, if you wouldn't mind?

Paul Egerman – eScription – CEO
Okay. So we have these two programs, we have the temporary program and we have the permanent program. So under the temporary program, you're going to have probably one, maybe two organizations that are authorized to be temporary testing and certification organizations. So you're going to have one or two organizations who are able to do that. Then hopefully sometime around the end of 2011, a year from now, the temporary program ends. And so the question is how do you decide when the temporary program ends and the permanent program begins?

One way you could do it, you could just say, as soon as you have one person who's able to be one organization site, it will do certification under the permanent program, you're going to end the temporary one.

The other way you could do it, is you just give it a specific date. So if you do the first thing, as soon as you're ready to rock and roll under the permanent program, you're going to stop everybody who's doing anything under the temporary one, which has a disadvantage perhaps that maybe there's two temporary certifiers, and one's qualified under the permanent program, but the second one just hasn't qualified yet. So you kind of, it immediately puts them out of business as soon as the first permanent group qualifies.

The second way you could do it would be to choose just the date, starting like 12/31, in which case you run the risk though of running two programs at the same time, where you have the temporary program still underway and the permanent program started up. That's the question is how do you decide when to end the temporary program and start the permanent one?

It's one of these things that like if you're doing like a contract with lawyers, you could burn up a lot of billable hours as they would figure something out. But it also could be one of these issues that we say,

it's interesting, but that's not an area that we want to make a recommendation, because it's not, it's administrative and it's not an issue.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
It's Scott. I think that might be the answer, Paul, the bit about the administrative issue.

Paul Egerman – eScription – CEO
It's an administrative issue and so we're not going to make a recommendation on it.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I think so.

Paul Egerman – eScription – CEO
And that's fine with me.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I don't hear anybody commenting on it, so I think that's a stronger position of anything.

Paul Egerman – eScription – CEO
Okay. And then having gone through all these issues, it's taking you through a lot of detail, let's take this up to a higher level. Does anybody have any other comments that they want to make about the temporary or the permanent program or about NPRM that we should consider for our recommendation?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Is there any standards being proposed with regard to turnaround time, weight list, and cues? One of the concerns that's out there is the distance between when rules will be final and when end users types to be required to be on operational software to meet stage two and stage three requirements. It's very short already. It'll lead to a very tight window for certification I'm assuming. Is there going to be a standard for turnaround time? How would we handle, what would likely be a very tight window where everyone needs to get certified quickly.

Paul Egerman – eScription – CEO
Those are two questions. The answer to the first question, again Suniti, correct me if I'm wrong or somebody correct me if I'm wrong, but as I read through this, I didn't see that there was any requirements for timeliness in terms of how fast people need to be tested and certified. There's nothing that says in by 9:00 out by 5:00 in this document.

Suniti Ponkshe – IBM Global Services – Associate Partner
Yes, you're right, Paul, but I think as we all know the industry is going to be pretty fast, because the timing of when they can get the incentive will drive the urgency.

Paul Egerman – eScription – CEO
That's correct, so I think there will be a lot of demand. And I think, at least what I'm personally hoping is by creating some competition that there's more than one certification organization and they really only get paid based on the number of organizations they actually certified and the number of vendors they actually certified. I'm hopeful that that gives us—

Scott White – 1199 SEIU – Assist. Director & Technology Project Director

That's an interesting question and I apologize if I should have read on that earlier, but is there any rate setting or rate limits to what they can charge? I'm just envisioning a very tight window. Will people basically buy their way up the priority cue? Is that regulated in any way.

Paul Egerman – eScription – CEO
Yes, that is also. No, there's nothing in here that says what the price is.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
It seems like we might be setting up a bad situation.

Suniti Ponkshe – IBM Global Services – Associate Partner
Paul, this is Sunitia. I think as far as pricing goes, that's kind of what the market will have to determine.

Paul Egerman – eScription – CEO
That's right. And I think there's some risk there, but I'd have to say my own observation is that people have a lot of concerns. So you just expressed a concern that this could be overpriced, it could be expensive. It's a concern that's been actually expressed twice at the policy committee meeting is there will be too many people who enter this marketplace and there would be like a race to the bottom, which would be more of a concern that the price would be cheap to do. It's hard to know, those are fears, and either side could really occur. My guess is that you're only going to end up with two or three organizations that are able to do this and that will be enough to give price competition and also hopefully service competition.

The question that you asked earlier about, how long it takes to get certified? And another way to look at it, that's sort of like service competition. How good a job do these organizations do? Are they friendly to their ineffective customers? Are they giving them helpful information in terms of if they're failing tests, why they're failing tests? How they're handling things? And hopefully, if you get at least two and maybe three, you'll have some level of competition.

But our job will be to monitor the process as it's rolled out to make sure it's going well, but this document doesn't address any of the pricing or timeliness issues and I personally don't think it should at this stage. I don't think we should be solving the problem before it exists.

So do we have any other comments about this document or concerns? And those concerns are very reasonable concerns that have been expressed. Any other comments in general about the certification process?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
None on mine.

Paul Egerman – eScription – CEO
Okay. So not hearing any others, I will write this up in the next few days, and I'll work with you, Paul Tang, to schedule a policy committee meeting, because our recommendations have to be approved by the policy committee before we can submit them, and it has to be done by April 9th. But I thank you for going through this, because I know it's a lot of detail, but this certification process is important, so I thank you very much for going through this.

So now if everybody's ready, we're going to like completely switch topics and go to patient safety. On patient safety issue if it's okay with everybody, what I'd really would like to do is take this document called the working document, I submitted a slight revision a few days ago, which is hopefully up on the HHS

Web site now, and sort of pick up where we left off; which is going through, there's like six or seven questions that are open topics for discussion to see if we can complete what's called the open topics.

And then I know we've gotten a number of e-mails and things from different people, suggestions about the whole document. But if we can complete running through it all, then we can try to put together like the next attempt at a final document, and try to look at that as a whole document. Is that approach okay with everybody in terms of walking through these six questions?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Sure.

Paul Egerman – eScription – CEO
Eight questions. Okay, the very first open topic for discussion was, do we want to have a recommendation for a special HIT patient safety course oversight function or an NTSB like editing that investigates serious patient concerns? And somebody asked and I forget who, Judy was one of our presenters, made a comment, it may have been a workgroup member who made a comment in an e-mail saying, why don't we just let the PSO organization do whatever the PSO organization does as opposed to try to do an organizational issue.

Does anybody else have any comment about any need for an oversight function support or should we just label that's more of a governance issue and we're not going to try and address that right now?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think it was Bill from HRQ was saying, the PSOs have the authority to do some of these things, but for one, they don't necessarily have the funding and there's lots of them. So we run the risk of if it's completely open, we run the risk of it being highly variable amongst the various PSOs, and then run the risk of not having anybody to actually aggregate some of the information from let's say the AB/PSOs and say, what are we learning here? So there might be some kind of notion.

The buck doesn't have to stop with ONC with even this committee's recommendation. We could say there might be another group that drills down on the various issues that we've uncovered that includes regulatory, liability, research in the area, public reporting, NTFB kind of function, and try to come up with a strategy for handling this issue. ONC could commission a group to look at the issue in more detail. Because I think leaving it totally open may not get us much further than we're now. Does that make any sense?

Paul Egerman – eScription – CEO
Yes. You're suggesting that instead of an oversight board though that there would be, be what? A group that—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
No, like an IOM study or something that goes and looks at the whole issue. We get such a small slice in such a short time to make recommendations. Part of our recommendations might be to enumerate the kinds of, it's almost like these questions. So one, we think there should be a protected way that both users and vendors can submit patient safety incidence; I'm just putting these on the table and then we can agree or not agree, two, we might think that there should be a way that the information across the country is collected and analyzed; three, there might be a way that, there might be some kind of entity that takes responsibility to drill down on things and try to get the lessons learned and then the dissemination.

This is a recount of some of the things we talked about in the policy committee, that those are actions that we think should happen with this information or data that's submitted. Now how it's done and what other protections you may or may not need in addition to what's provided by the patient safety organization law, this has to be looked into.

Paul Egerman – eScription – CEO
Okay. And so that makes sense and you made a good comment, Paul, when you talked about possibly an IOM study, because one of the things that I forgot to mention that what I put in this draft, I did put in that concept. I don't know if you have the draft in front of you, but I did change the wording a little bit from something that was said earlier, I said all these recommendations are necessary by themselves and do not represent a complete response to all HIT patient safety concerns. And I said for example, there may be areas that PSO data does not cover, then I said additional research is needed, and I said a formal independent evaluation of current patient safety issues is recommended.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Well both the issues and an appropriate response strategy dealing with those.

Paul Egerman – eScription – CEO
So that's some sense of independent evaluation of some issues and response.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes.

Paul Egerman – eScription – CEO
And I think that's—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
A way of addressing those issues. So we're looking at, we've uncovered a lot of the issues, but to organize it and putting it together and organizing framework and a way of addressing that on behalf of the country as part of this learning health system, it makes you do a lot more work than what we had the time to do.

Paul Egerman – eScription – CEO
Yes, and that's an excellent comment, because when you think about it, putting together a patient safety structure for the entire country sounds like kind of a daunting prospect and to think that we could do that like in a six-hour or four-hour hearing and then have it all wrapped up, it's nice, but even though we're very good, I don't think we're quite that good. And so to say a formal independent evaluation of the issues, and the correct response is recommended, and the formal—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
But for a strategy for responding, because you want it not to just stop the problem fitness.

Paul Egerman – eScription – CEO
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And that's a service I think this advisory committee is making to ONC.

Paul Egerman – eScription – CEO

Yes, I think that's correct, that's an excellent comment. Let me just ask, do other people want to react to that? Are there any other comments from other workgroup members? In following your comment, Paul, you listen to these things, patients and vendors, and I'll say healthcare organizations need to be able to report problems.

The question I have is should we be talking about those issues in just a very generic way like that or should we still be in our recommendations talking about patient safety organization or maybe make patient safety organization as an example of how we would accomplish these issues?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. I think it's an example and because it has a number of those important attributes. So one, it does have legal protection as far as liability, at least to the extent that we've discussed so far. You can submit confidential reports, the organizations can, but they're not forced to, do further investigations while maintaining confidentiality, and they can create uniform structures, remember what Bill talked about, format for reporting.

But it seems like all of these things are permissive, but not required, and it might take an organizing entity and we don't know what that is. We toyed with the idea of FDA, but there may be other ways of doing it within the PSO structure. But anyway, that's sort of beyond what we should recommend. It seems like we need to identify the attributes.

One, do we believe that the problem exists? And I think we sort of said, yes; two, do we think it's adequately addressed now? And I think some of us are saying, no; and three, then how can we more fully develop the types of issues that are out there and come up with a strategy for addressing them on a national level so that we can ensure that these systems are safe and effective? And that ONC probably would turn to some independent group that's especially structured for that with the right expertise to delve down into these issues.

Paul Egerman – eScription – CEO
Okay, that makes sense. And that makes sense in terms of how to structure and frame our recommendation and also how to answer this first question. And again, I want to make sure that it's not just the two of us talking.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes.

Paul Egerman – eScription – CEO
Anybody else have comments about this, are you comfortable with what Paul just said?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I'm comfortable with it, it's Scott.

Paul Egerman – eScription – CEO
Okay. So continuing on my list, and so what I'll do, I'll do my best to like reframe this working document around those concepts and we'll send that out hopefully by sometime over the weekend. But very helpful comments, Paul, I really appreciate that.

The second open topic that we have for discussion was interoperability was identified as a patient safety issue. Is that something that this workgroup should respond to in some way?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We certainly may have an opinion that the lack of interoperability contributes to patient safety issues, and that just heightens the need for ONC through its programs to develop and recognize appropriate standards and incorporate that into its certification programs.

Paul Egerman – eScription – CEO
Okay, and that's fine, because on this issue, Carl Dvorak is not on this call.

Carl Dvorak – Epic Systems - EVP
Yes, he is.

Paul Egerman – eScription – CEO
Okay. I'll first say a call from Carl, I didn't know you were on the call, you had taken exception, if I remember right, to the first way this was drafted in which to suggest that because of patient safety, we should somehow expand our efforts on interoperability. Are you comfortable with what Paul Tang just said?

Carl Dvorak – Epic Systems - EVP
I think so. I think that's a basic recommendation to the people who are defining interoperability standards to keep patient safety in mind and address it as they create the standards. My real concern was to differentiate this notion of a sort of modular snap in pieces within a health system interoperability as compared to a health system to health system interoperability.

And I think the ONC should try to factor in safety discussions with regard to the health system to health system interoperability. But I'm not sure that within a health system, other than possibly a site certification or a leap frog flight simulator sort of test, I'm not sure what action steps they could really take, because how those pieces are snapped together in the alignment of the different paradigms and the alignment in ... coding systems are going to be so highly variable that I don't know that it's something that the group could even really tackle and come out the other side with an effective strategy for.

Paul Egerman – eScription – CEO
Okay. One of the interesting things, I thought about this issue a little bit, one of the interesting things is I suspect a lot of people don't understand, at least for large organizations, like just say Intermountain Healthcare, how many vendors and systems and interfaces that exist? And I suspect it's not unusual to see organizations with a hundred different systems in place, and that's one of the reasons why this whole argument is so challenging. I don't know if that observation is helpful to make, but large organizations have lots and lots of different applications and lots of different sources.

Chris Brancato – Deloitte – Manager, Health Information Technology
Paul, it's Chris Brancato. I want to raise an issue that's either overarching or underpinning everything that you've discussed here in regards to patient safety, and that is, how do you actually get the information forensically to determine that there was an issue? So where I'm going with this is, there were recommendations that came out of the privacy and security workgroup and others talking about audibility, and the ability to have standards as part of a system to create the audit trail to investigate the very things that you're identifying.

Paul Egerman – eScription – CEO
I have to understand what you're raising, Chris. You're raising an issue that, you're talking about interoperability, something goes wrong, how do you find out what really happened?

Chris Brancato – Deloitte – Manager, Health Information Technology
Correct, absolutely.

Paul Egerman – eScription – CEO
...

Chris Brancato – Deloitte – Manager, Health Information Technology
I think it's appropriate for this workgroup to consider making recommendations. We recognize that patient safety investigations require the ability to audit these systems, integrated or not, modular or not.

Paul Egerman – eScription – CEO
Now what does that mean, auditing systems? Can you explain what you mean by that?

Chris Brancato – Deloitte – Manager, Health Information Technology
I guess the expectation from a technology and a critical point of view was, if I use a disparate system, that system, a modular system, has to have an ability for me to audit it, track it down, possibly to the data element level of, did the error or the safety alert or concern happen because there was an entry error, or did the database get corrupted? See where I'm going? There has to be a mechanism. So let's say you integrate that module with another module, well you've introduced another area where data transfers or transforms, where that function has to be audited as well. So what you're looking for at the end of the day is traceability. Where did the error occur and more importantly who can I attribute it to?

Paul Egerman – eScription – CEO
It's a fascinating issue, and listen, on one hand, it all makes sense, on the other hand, I'm not sure I understand how you make sure these systems, as you put it, vulnerable and traceable?

Chris Brancato – Deloitte – Manager, Health Information Technology
I think, again, what's appropriate for the consideration here for this workgroup is, a consideration that we recognize that we're raising these issues that are potential policy issues. And at some point, we have to recognize some recommendations to ONC or to the policy committee as a whole that the standards committee may have to consider this.

In order to address this issue, there's a technical component that either through standards and certification criteria that in order to improve patient safety the systems themselves have to have the functionality to do that.

Paul Egerman – eScription – CEO
Yes, and actually that's a great observation. Let me try to write something up on that, now that you've spoken it and I understand it. Yes, I read through the FDA material, which again I appreciate the FDA given us their raw data, it's very helpful, and as I recall, there was one example, where it was something like a tax system, which was actually related to unfortunately the death of a patient where there was some issue that something had shown up on an image and the radiologist hadn't read it correctly. And the radiologist said, "Well it didn't show up correctly on my screen and that's why I didn't read it correctly," and the vendor said, "Well sure it didn't show up correctly and we checked." And so that's sort of an example of the traceability or what you call the forensic aspect of the thing where you have those kinds of disputes that go on. So that's a very interesting issue.

So getting back to the topic of interoperability then, what we're going to do is we're going to say what we've learned about patient safety reinforces our concept that it is an important topic. So we're going to

try to raise this issue of traceability as an important issue for discussion and evaluation, that sounds great.

And then the next open issue that we had and we saw it come out a little bit was this issue of whistle blowing protection, which is an issue that you raised, Scott. As I raise that, Bill Munea, I hope I pronounced his name correctly, sent me an e-mail with more information about how patient safety organizations work, and I sort of wrote that all up. But basically it says that the patient safety ap includes what he called "reporter protections" that gives an employee a right of action if somebody takes an adverse action against them for reporting and then it also talked about how to make things confidential.

And so my question is, is that information an adequate response to this question? I don't know, Scott, do you have other things you want to talk about this issue or if other people want to talk some more about the whole issue of whistle blower protection?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Hello, Paul, it's Scott. A, yes, it addresses the issue that I raised, but the B to it, it seemed that the comments from the FDA in their protections, which was kind of where this came out of, if we're recommending a PSO concept, does this fall under the PSOs as well? But the concept, I think was consistent with what I'm looking for, I'm just concerned that its enforcement is appropriate if we choose to go one way or the other.

Paul Egerman – eScription – CEO
Yes, if I heard that right, Scott, the main thing you want to make sure of, and this is going to be handled the way I write up Paul Tang's suggestion, that there's some methodology for people to report these patient safety issues in a protected way. In other words, they can either do it confidentially, they have a sense of confidence that something bad is not going to happen to them because they report something.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Absolutely, I mean to go a half of step further, I would advocate that should there be actions taken against somebody. It's one thing to have a system, but if the system fails and somebody still takes an action, that should have some sort of penalty contained within it as well.

Paul Egerman – eScription – CEO
I didn't understand the last thing you said, could you repeat that again?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Sure. It's one thing to have a system that says the systems confidential and we don't designate who's making the call, but there's a fear that somehow it does come out and somebody does retaliate. So one, is the process being as confidential as possible, but two, should somebody take retaliation, that there should be some sort of penalty if will you or stick as we like to use for that type of action.

Paul Egerman – eScription – CEO
Okay, now I understand it. And again, what Bill wrote here seems to respond to that.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I agree.

Paul Egerman – eScription – CEO
That information is confidential and privileged, but there's also this protection against, whatever the wording is, that adverse personnel action. Yes, that certainly sounds like euphemism for getting your

head cut off. Basically, that's what you're asking, you want to make sure both of those things are in place as protection.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Right.

Paul Egerman – eScription – CEO
Okay, that's fine.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Right, yes, but just my question to anybody in the group or yourself, Paul, it seemed that under the FDA there was these types of protections, but my question is under these other entities that we're calling PSOs and there seems to be a number of them, how do we ensure the protection to those reporting these issues in these 70 or so other organizations? Do they have the same stick if you will?

Paul Egerman – eScription – CEO
Well—

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
That's my only question.

Paul Egerman – eScription – CEO
I mean, first off—

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
And if they do, then the answer is, I'm fine with the concept that we just laid out.

Paul Egerman – eScription – CEO
Yes. What Bill was telling us, is yes, they do, and he's sort of citing the section of the act, so that was very specific, and so he says, yes, they do. And so we invited him to be a member of this workgroup, and he apparently agreed to join, which is terrific. He just didn't make today's meeting, but hopefully in one of the next meetings he could give us some more information.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
Then I'm fine, Paul.

Paul Egerman – eScription – CEO
Okay, great. The next issue is the issue of the accreditation organizations, which I think Joan, if I remember right, you were the person who raised this issue.

Joan Ash
Well, yes, plus the Joint Commission did testify to us.

Paul Egerman – eScription – CEO
That's correct. What would you like to say about that, Joan?

Joan Ash
Just that seems that we should encourage them to have a role, I'm not sure what, but they already have such a powerful role in ensuring patient safety, not necessarily IT patient safety, but it seems like they should be encouraged to step up their role for HIT safety. And maybe, I think it was Gil Cooperman who

recommended that we might say something about encouraging HIT safety committees in larger organizations, and I think that's a very good point and something that maybe we could recommend that the Joint Commission look at.

Paul Egerman – eScription – CEO
That's great. Although, we could recommend that the Joint Commission look at it, but we really make a recommendations to ONC. So it's really a recommendation that the national coordinator work with the Joint Commission.

Joan Ash
Perfect.

Paul Egerman – eScription – CEO
Yes, to do that.

Joan Ash
Yes.

Paul Egerman – eScription – CEO
But actually as I think about it and if I'm hearing you right, this could be a very important thing, because what Mark Probst is pointing out is it's all about having like a culture of improvement within the organization. And fundamentally, there's a lot of elements in making sure that that culture improvement exists, and an organization like the Joint Commission could help a lot in making sure that that occurs, just like an auditing firm to make sure that there are systems with controls in place. I think that's very helpful.

Joan Ash
Well, the other thing about the Joint Commission is they're the ones that go onsite and spend time and look and sense the culture while they're there, and this is a way of taking advantage of that to promote safety.

Paul Egerman – eScription – CEO
Great, good comments, excellent. Okay, thank you, Joan. The next question that I have here and I'll do my best to write it up, Joan. Whatever I write up, hopefully you will fix and I'll be sure that if I use the word data ...

Joan Ash
Thank you.

Paul Egerman – eScription – CEO
I've learned a lot. The next question is this issue of small physician groups in rural hospitals or safety net institutions, which as we consider all these things, do we think there's anything special that has to happen for those organizations? Is that something we'll just wait for the study to evaluate?

And Michael Sterns made a comment that I put in here, but he basically indicated that if I understand it right that he has heard a lot less in an ambulatory space about issues, but it doesn't necessarily mean that they aren't incurring, he just thinks that perhaps it's not being reported as frequently. I haven't heard anybody say that we really need to do anything special for these groups. I don't know if anybody has any comment on this?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

This is Paul Tang, like usual, they have fewer resources to be able to investigate these things. I think they're just more vulnerable in that regard. So the issue still remains and wouldn't not impact these folks. I will say that we have this problem in the space in the ambulatory. I don't think we should say that there's less of this problem in the ambulatory HIT, and it's not likely to be less so in rural or safety net hospitals too. I think we need to benefit everybody by acting on this.

Paul Egerman – eScription – CEO
Okay. I'm also assuming that what we're doing doesn't appear to have a big administrative burden to report. So even if they have a small administrative staff, we're not placing any special burden on them that's difficult for a solo physician to respond to.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We're actually helping them by trying to work some of these easier reporter mechanisms into the EHRs themselves.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
That's right. Paul, it's Scott. I wish Joe Hannon was here, because he has been such a strong advocate for the small physician groups and some of their peculiarities as these recommendations come along. I know he's not here, but when we come up with suggestions really pushing to make comment of this, I think his perspective is so valuable here.

Paul Egerman – eScription – CEO
That's true. Although, as I think about it, everything is connected these days. So solo practitioners, a solo physician, probably practices his admitting privileges at a large integrated delivery network; and a rural hospital probably has a relationship with a larger healthcare organization to transfer patients. And in that process, they probably are exposed to patient safety issues of the other organizations, so they end up becoming participants in this process. I agree with you, let's try to get some feedback from Joe on this issue.

Joan Ash
The other thing I don't think we should forget is we were trying to figure out the role of the regional extension centers in this, and again, I think it was Gil Cooperman who mentioned that they might play a role. We've already mentioned a role they could play in training, but maybe there's another role they could play to help ensure patient safety in this sort of environment.

Paul Egerman – eScription – CEO
How would they do that?

Joan Ash
I don't know. I don't know. But again, they're going to be out there, they're the ones who are going to be touching the small practices the most. If there are going to be reporting, any kind of reporting requirements, they could help assure that they get done or teach or I don't know.

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
It seems if they could provide some best practices that are being applied through their areas, so that seems to be an obvious one. But Joan's right, they're the umbrella over a lot of this stuff that we could use just from a learning setting.

Paul Egerman – eScription – CEO

In other words, put up the sites being, helping with training, they could also be like just a general resources. It's one thing to get trained, but if you're trained on something, you'd like to be able to call and say, "Listen, I just saw this happen at abc hospital, what should I do?"

Joan Ash
A communication conduit, right.

Paul Egerman – eScription – CEO
Yes. That's excellent, terrific, thank you. Those are good comments about the physician groups in rural hospitals. The next item that was on the list is the relationship between instant reporting and liabilities. I don't know if we feel like we've already covered that issue. Again, I put this down, I think it was based on an e-mail that you had sent me, Scott, so do you feel that we've already covered that issue or is there some additional discussion you want on that topic, Scott?

Scott White – 1199 SEIU – Assist. Director & Technology Project Director
I must be having a senior moment, I don't remember what I sent to you, but then again, we've had a lot of communications all of us back and forth. I don't know if I have a comment on it at the moment, Paul.

Paul Egerman – eScription – CEO
Okay, and that's fine. The way I put together this list is in the course of like people send me e-mails or in discussions, if somebody raised an issue, I just wrote it down on the list, and said we'll talk about it and make sure everybody's issues were covered, so if you feel comfortable that it was talked about, that's great.

The next issue, I think this was an issue that Carl raised was the speed of introducing stage two and three. In other words, I think a lot of people have some concern about the speed in which we're progressing. It's like a patient safety issue as to how fast and what's the time period for stage two introduction and stage three and how we get the software and everything done. And so if you're still on the call, Carl.

Carl Dvorak – Epic Systems - EVP
I'm here.

Paul Egerman – eScription – CEO
Am I saying this correctly?

Carl Dvorak – Epic Systems - EVP
Yes. I think the problem is basically the time between when the rules come out and are final, before a customer has to have them implemented in production to qualify is too short. And we would recommend moving the requirement for completing the definition significantly forward in the calendar to leave enough time to design, implement, test, give to a customer, let them test in their environment, do appropriate training, and get into production for the requirement period.

Paul Egerman – eScription – CEO
Do you have a specific? In other words, you say it's too short. I think we do best if like we're really specific.

Carl Dvorak – Epic Systems - EVP
Yes.

Paul Egerman – eScription – CEO
Because short versus long.

Carl Dvorak – Epic Systems - EVP
Let me pull the date, but I sent them in the document yesterday, so let me—

Paul Egerman – eScription – CEO
That's right, so you may have, I'm sorry.

Carl Dvorak – Epic Systems - EVP
Yes, a sentence in there about the specific date, I just want to pull it up.

Paul Egerman – eScription – CEO
What you said, Carl, was stage two by the end of 2010, and stage three by the end of 2012.

Carl Dvorak – Epic Systems - EVP
Yes, 2012, yes.

Paul Egerman – eScription – CEO
I think that's fine. But let me throw like a curve ball at you and everybody, in terms of the IFR, in terms of what the software is supposed to do, why can't you do stage two and stage three all at the same time? Why do you have to have a stage three? Why can't you just announce, here's everything you need to do for both stage two and stage three? And you still have the stages, and the stages could be on what percentage of utilization you have to do or maybe the software does have some functionality that you don't need for stage two, but you might need for stage three. Why do you even need a stage three as a software?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang. As you know from sort of the strategic plan document that's evolving right now, the whole notion is that this is a learning health system, and probably that this discussion actually ties into, we have to learn about both EHRs and the appropriate use of them, and deploying them in a safe and effective manner.

One of the reasons for the multiple stages is because we want to learn from what happens with stage one implementation and certification and achieving the incentive. Although, it's nice and one of our goals, our meaningful use workgroup goals, is to layout sort of a glide path or a roadmap. Because it's so early on, it's hard to predict how it may change in stage two, especially I guess in stage three, so that's the reason.

I think one approach would have been to have, here's the entire stage three and here's the percent of the criteria you have to meet in stage one and two. I think the other thought is that we can't actually do that now because so little is known. As you know, a comprehensive EHR exists in less than 10% of both practices and hospitals. So as the industry and the provider community ramp up, we're likely to learn things that would affect stage two and three requirements.

Paul Egerman – eScription – CEO
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's the thought.

Paul Egerman – eScription – CEO
Okay.

Carl Dvorak – Epic Systems – EVP
I think you could argue that for stage three, but I think the horse has left the barn on stage two. The eligibility period being able to bump back to the last three months and then bumping right into the stage three requirement, I just don't know if there's enough time to really learn and process through that, anything really substantially beyond what we already know today.

Paul Egerman – eScription – CEO
I think that's a fair comment, Carl, and I think that kind of a sentiment should be taken into account as the workgroup plans what modification might be made to the stage one criteria in stage two, and I think you make a very valid observation.

Carl Dvorak – Epic Systems - EVP
So maybe move stage three, maybe you don't have to be as aggressive on stage three, although, if we anticipate anything major, again, that sort of larger window is nice, and try to pull stage two forward as much as we can at this point.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, that's fair. And so the workgroup is marching on its hearing schedule to try to find some mechanism to signal the industry and the providers by the end of this year, which would be, now that doesn't mean that CMS would have its final, and I don't know what you meant by finalized standards, but we hope to have some kind of indication by the end of this year at least to help.

Paul Egerman – eScription – CEO
Yes, it does, 2010.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes.

Paul Egerman – eScription – CEO
But what Carl is suggesting that you finalize the standards.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I know.

Paul Egerman – eScription – CEO
When you said finalize standards, Carl, what did you mean?

Carl Dvorak – Epic Systems - EVP
I think the original anticipation was that certification requirements would be out ahead of meaningful use. And from the field of what was required in certification, the people who constructed meaningful use would assemble pieces that they thought would make a difference. And that's sort of how I thought it was envisioned originally.

By done, I think what we're really looking for is, what are the specific features and functions that we'll have to certify against?

Paul Egerman – eScription – CEO
Okay. If I heard what you just said and I'm trying to interpret it into the regulatory things that we've recently learned about, at least I recently learned about. If I'm interpreting correctly what you're saying is by the end of 2010, you'd like to see an IFR published for stage two?

Carl Dvorak – Epic Systems - EVP
Yes.

Paul Egerman – eScription – CEO
And I'm taking a guess that that is one of these things that might sound good, but might be very hard to get done. What do you think, Paul, is this possible to do?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, I think it would be hard to do, but as an alternative could there be enough output from the policy committee, from the meaningful use workgroup, that would help paint a clearer picture of what stage two might look like, at least a recommendation for stage two? And while that's not final, it could help with planning.

Carl Dvorak – Epic Systems - EVP
What is odd and we might want to tackle is, many of our sites have commented on this that they're likely to be able to achieve meaningful use even though the version they're on is not certified. So another piece to the puzzle might be to allow more variance, if a site is substantially complying with meaningful use, not to require them to be on a certified version for stage two, or maybe offer some preliminary stage two certifications early in the process to the best of our ability based on what we know, but not require them to be on a final stage two certification, provided that they can accomplish meaningful use.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Certification actually is one of the powerful leavers I think that's part of the high-tech program.

Paul Egerman – eScription – CEO
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And here's an example, most of category three and four, which is care coordination and public and population health are not, the biggest impact is actually on the vendor and the products that's really implementing the standards for interoperability in helping with information exchange. And that's mostly, because it's basically a capability in test one's kind of a requirement, at least in the NPRM, that's really the vendors being able to create that functionality in demonstrating that it would work. So that's something that we don't have right now for example, so you'd almost have to rely on the certification to prove that.

Carl Dvorak – Epic Systems - EVP
Right, so my suggestion would be this, if we can sketch it out in more or less complete terms early, then we could have the certifiers offer preliminary certification. And in end user sites that was at least live on a preliminarily certified version could still be eligible for meaningful use for stage two or I guess stage three, maybe they couldn't advance passed that stage until they were officially on filed certified versions for that stage. I'm just very concerned with sort of the forcing of upgrades through organizations.

Paul Egerman – eScription – CEO

Yes. I think it's a good suggestion, Carl, but I think we've got a complicated enough program to introduce the new certification concept or stage is really confusing.

Carl Dvorak – Epic Systems - EVP
I would just fall back then to move the date, the finalized requirements, so that it's early enough that you could do a proper development, testing, delivery, implementation, training, and adoption cycle.

Paul Egerman – eScription – CEO
Yes, so what I'm wondering is the right way to do this is to take what you wrote here and somehow think a little bit more about the specific dates. In other words, to try to figure out, what could we move up? In other words, let's rephrase this that we want to make a suggestion for an earlier date for the IFR for stage two, and what's a reasonable earlier date that we can do that we think ONC can actually accomplish, and also still meet the basic concept as to what you're trying to accomplish, Carl. Which I haven't heard any disagreement, I think your point is an excellent point and is an important thing to do. I don't know what I said made any sense, but hopefully there's a date after the end of 2010 that you still think would be okay. Can you tell me, Paul Tang, how we could get some guidance as to what that date could be that's realistic or achievable?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
For the IFR?

Paul Egerman – eScription – CEO
For the IFR. So the IFR could proceed the NPRM on meaningful use, right?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
How could it do that?

Paul Egerman – eScription – CEO
Well, it could if you knew enough about stage two of meaningful use, that you knew what you wanted to do, but you didn't quite know, sort of like the quantity. In other words, you were debating whether or not a 10% CPOE was going to be increased to 20% or 50%.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, that would be irrelevant for the IFR.

Paul Egerman – eScription – CEO
It would be irrelevant for the IFR, yes. The part that's relevant is if there's some additional functionality or some additional interface—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right.

Paul Egerman – eScription – CEO
—that's needed. So that's what I say, you'd have to know a fair amount about the IFR, the NPRM and the meaningful use thing.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right.

Paul Egerman – eScription – CEO

But you don't necessarily have to have the whole thing nailed down. But probably it's going to end up that you're going to do them at the same time anyway, would be my guess.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
They, meaning ONC and CMS—

Paul Egerman – eScription – CEO
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
—already have to have had prior knowledge internally about what their plans are to issue a useful IFR. I'm a bit intrigued by Carl's suggestion about this whole, the timing predicament about 2013. I could see, so this is totally hypothetical, there could be a scenario where the meaningful use recommendations that emerge for the criteria for 2013 could not be substantially different from a requirement of the EHR point of view. It's how you use it, that it's possible in a hypothetical case that ONC could deem stage one certification to meet the requirements for stage two certification, that's not saying that meaningful use requirements wouldn't change, but the certification requirements of EHR potentially could not change.

But anyway, I think these are things that should be taken into account as we develop the 2013 program criteria recommendations. But I don't know how the IFR can be issued ahead of a better, at least the recommendation from the committee, it's not the NPRM.

Paul Egerman – eScription – CEO
But essentially, Paul, because what you just said is in effect a variation of my original suggestion. In other words, you could find yourself in a situation for stage three for meaningful use.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right.

Paul Egerman – eScription – CEO
And you have no choice but to use what was already announced for stage two, because there's not enough time to get anything significant out the door.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right.

Paul Egerman – eScription – CEO
So in effect, you may have discovered that you implemented my proposal by accident.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's right, yes, that's right. And it's more likely that 2013 stage two would be closer to one, than three would be closer to one.

Paul Egerman – eScription – CEO
Okay. So what do we do about this issue about face, where do we have this discussion next? Do we just want to say, shorter urgency, or do we want to say something more specific?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think this is a little out of context of EHR safety, good call, Paul, we wanted to get it in there anyway.

Carl Dvorak – Epic Systems - EVP
Well, I think it is—

Paul Egerman – eScription – CEO
I don't think it is—

Carl Dvorak – Epic Systems - EVP
It is a safety issue, because one thing I think history does show us, if you try to push things out faster or undermine the fundamentals of doing appropriate cycles ... and things like that, design reviews, I think we're going to set people up in a race to get this money; to slam things out the door that just simply don't go through the level of process and attention to detail that they likely need to, especially as these requirements now start to get more sophisticated.

Paul Egerman – eScription – CEO
Yes, there's a lot of work on the side of the healthcare organization to test the software before they roll it out, and when you roll out new stuff, it is a safety issue.

Carl Dvorak – Epic Systems - EVP
That's true, it's a fair point.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
So Carl's recommendations stand, in other words, we need enough we, everyone, needs enough time to safely develop and implement these safety functions.

Paul Egerman – eScription – CEO
Unfortunately, we're out of time, because we also have to have public comment. I don't know what I'll write up, I'll write up something on this topic. So let me tell you, and we didn't get to the last topic.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Which was the most important probably.

Paul Egerman – eScription – CEO
It's sort of like saving the most interesting and controversial for last, which is the various FDA things, which I did write up something on. But first, to summarize what we've done, I'm going to do my best to write up all these materials, and I'll work with the ONC staff on this, and we have another call scheduled, I think it's 10:00 Monday morning. What we're going to try to do with the call is hopefully quickly review whatever I write up about the NPRM, but then talk about this FDA discussion, and review whatever draft document we have to see if we're closing in on this discussion. But all together, I think this has really been an excellent discussion.

I want to thank everybody for participating. This is a lot of material that we're covering and it's been very interesting, so thank you very much. And I don't know if we have any members of the public who want to make comments, I know we're short on time. I don't know if the workgroup members have time to stay, but I'm willing to stay passed 1:00 if there are members of the public who also want to make comments. So Judy, can you take care of opening the line for public comment?

Judy Sparrow – Office of the National Coordinator – Executive Director
Sure, operator, can you check and see if anyone wishes to star one?

Moderator

For those who are listening via the Web, please dial 1-877-705-2976 and press star one to be placed into the comment queue. Those who are already on the phone, please press star one at this time.

We do not have any public comments at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great, thank you, Paul, thanks, everybody.

Paul Egerman – eScription – CEO
Thank you, Judy. Thank you, Jonathan, and members of the ONC staff, and thank you, workgroup members. And I guess at 10:00 on Monday, I know it's a lot needs, but I really appreciate it, and we're making huge progress.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes. Goodbye.

Paul Egerman – eScription – CEO
Goodbye.